



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,329	03/05/2002	Alan A. Winder	41482/205543	9927

30559 7590 12/10/2003

CHIEF PATENT COUNSEL
SMITH & NEPHEW, INC.
1450 BROOKS ROAD
MEMPHIS, TN 38116

EXAMINER

SMITH, RUTH S

ART UNIT	PAPER NUMBER
----------	--------------

3737

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,329

Applicant(s)

WINDER ET AL.

Examiner

Ruth S Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5,21 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger. The claims are directly readable on Unger which discloses a method for treating a patient comprising introducing an ultrasound contrast agent into a patient, impinging ultrasound waves in proximity to the treatment area, wherein the ultrasound contrast agent facilitates in lowering the cavitation threshold (see column 10, lines 42-45). The intensity of the ultrasound is maintained in the range as set forth in claim 2 (see column 10, lines 46-48). The contrast agent is comprised of microbubbles having a radius in the range set forth in claims 3,21 (see column 15, lines 17-19). With regard to claim 4, resonant bubble frequency as set forth is inherent in the operating parameters of the system and the microbubbles used. With regard to claim 5, the frequency of the ultrasound used is within the range set forth (see the examples used in columns 40, 41,43).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unger. Unger discloses a method for treating a patient comprising introducing an ultrasound contrast agent into a patient, impinging ultrasound waves in proximity to the treatment area, wherein the ultrasound contrast agent facilitates in lowering the cavitation threshold (see column 10, lines 42-45). Unger fails to specifically disclose the treatment time set forth. Unger discloses that the ultrasound can be applied until the desired effect is achieved. In the absence of any showing of criticality, the specific time that the treatment lasts would have been obvious to one skilled in the art and could be determined without undue experimentation as the time it takes for the desired effect to be achieved.

Claims 7-10,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger in view of Unger et al. Unger discloses a method for treating a patient comprising introducing an ultrasound contrast agent into a patient, impinging ultrasound waves in proximity to the treatment area, wherein the ultrasound contrast agent facilitates in lowering the cavitation threshold (see column 10, lines 42-45). Unger does not specifically disclose the manner in which the contrast agent is introduced into the patient. Unger et al disclose a delivery system for delivering a material into a patient via microbubbles. The microtubules can be intravenously introduced into the patient using a syringe. Furthermore, the material in the microbubbles is released via the application of energy over time and is therefore considered to be time-released forms of

application. In the absence of any showing of criticality, the manner in which the contrast agent is introduced into the patient would have been a matter of design choice of known equivalents in the art.

Claims 11,15-20,23,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger in view of Talish et al. Unger discloses a method for treating a patient comprising introducing an ultrasound contrast agent into a patient, impinging ultrasound waves in proximity to the treatment area, wherein the ultrasound contrast agent facilitates in lowering the cavitation threshold (see column 10, lines 42-45). The contrast agent is comprised of microbubbles having a radius in the range set forth in claims 15,23 (see column 15, lines 17-19). Unger fails to specifically disclose the structure of the ultrasound device for applying the therapeutic ultrasound. Talish et al disclose an apparatus for applying therapeutic ultrasound to treat areas in a patient. The structure disclosed by Talish includes all the ultrasound elements as set forth in the claims. It would have been obvious to one skilled in the art to have modified Unger such that the device used to provide the ultrasound is as taught by Talish et al. Such a modification would have merely involves the selection of one known type of ultrasound application device for therapeutic applications.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger in view of Talish et al as applied to claim 11 above, and further in view of Unger et al. Unger et al disclose a delivery system for delivering a material into a patient via microbubbles. The microtubules can be intravenously introduced into the patient using a syringe. Furthermore, the material in the microbubbles is released via the application of energy over time and is therefore considered to be time-released forms of application. In the absence of any showing of criticality, the manner in which the contrast agent is introduced into the patient would have been a matter of design choice of known equivalents in the art. It would have been obvious to one skilled in the art to have further modified Unger such that the microbubbles are introduced via an IV using a syringe in a time released manner as disclosed by Unger et al. Such a modification

merely involves the selection of a well known means for introduction of a material into a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Ruth S Smith
Primary Examiner
Art Unit 3737

RSS